

**Form PTO-1449 (modified)****List of Patents and Publications for Applicant's****INFORMATION DISCLOSURE STATEMENT**

(Use several sheets if necessary)

Atty. Docket No.  
NUBI:002/FUSSerial No.  
08/912,978

Applicant

Rajendra Aneja

Filing Date:  
August 13, 1997Group:  
1502U.S. Patent Documents  
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See Page 1Other Art  
See Page 1**U.S. Patent Documents**

| Exam. Init. | Ref. Des. | Document Number | Date     | Name                       | Class | Sub Class | Filing Date if App. |
|-------------|-----------|-----------------|----------|----------------------------|-------|-----------|---------------------|
| <i>h</i>    | A1        | 4,772,471       | 09/20/88 | Vanlerberghe <i>et al.</i> | 424   | 450       | 12/12/79            |
|             | A2        | 4,830,857       | 05/16/89 | Handjani <i>et al.</i>     | 424   | 450       | 10/21/85            |
|             | A3        | 4,837,028       | 06/06/89 | Allen                      | 424   | 450       | 12/24/86            |
|             | A4        | 4,920,016       | 04/24/90 | Allen <i>et al.</i>        | 424   | 450       | 12/18/87            |
|             | A5        | 5,013,556       | 05/07/91 | Woodle <i>et al.</i>       | 424   | 450       | 10/20/89            |
|             | A6        | 5,153,000       | 10/06/92 | Chikawa <i>et al.</i>      | 424   | 450       | 11/16/89            |
|             | A7        | 5,225,212       | 07/06/93 | Martin <i>et al.</i>       | 424   | 450       | 12/10/90            |
| <i>h</i>    | A8        | 5,395,619       | 03/07/95 | Zalipsky <i>et al.</i>     | 424   | 450       | 03/03/93            |

**Foreign Patent Documents**

| Exam. Init. | Ref. Des. | Document Number | Date     | Country | Class | Sub Class | Translation Yes/No |
|-------------|-----------|-----------------|----------|---------|-------|-----------|--------------------|
| <i>h</i>    | B1        | EP 0370491      | 04-19-95 | Europe  |       |           |                    |

**Other Art (Including Author, Title, Date Pertinent Pages, Etc.)**

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| <i>h</i>    | C1        | Allen and Chonn, "Large unilamellar liposomes with low uptake into the reticuloendothelial system," <i>FEBS Lett.</i> , 223(1):42-46, 1987.  |
| <i>h</i>    | C2        | Allen, Hansen, Martin, Redemann, Yau-Young, "Liposomes containing synthetic lipid derivatives of poly(ethylene glycol) show prolonged circulation half-lives <i>in vivo</i> ," <i>Biochim. Biophys. Acta</i> , 1066:29-36, 1991. |
| <i>h</i>    | C3        | Amselem, Cohen, Barenholz, " <i>In vitro</i> tests to predict <i>in vivo</i> performance of liposomal dosage forms," <i>Chem. Phys. Lipids</i> , 64:219-237, 1993.   |

Examiner:

*Karla*

Date Considered:

6/4/07

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|             | C4        | Aneja, "Structural and stereochemical purity of glycerophospholipids," <i>Biochem. Soc. Trans.</i> , 2:38-41:1974.   |
|             | C5        | Aneja, "Novel biomolecular approaches to steric stabilization of liposomes: materials and organization," An American Chemical Society Symposium, ACS Annual Meeting, Sept. 8-11, Las Vegas, NV, 1977.  |
|             | C6        | Aneja, "Novel biomaterials for optimizing liposomal drug delivery," 213th ACS National Meeting of the American Chemical Society, San Francisco, California, USA, <i>Abstracts of Papers American Chemical Society</i> , 213:(1-3), Abstract BIOT-003, April 13-17, 1997. |
|             | C7        | Aneja, Chadha, Davies, "A general synthesis of glycerophospholipids," <i>Biochim. Biophys. Acta</i> , 218:102-111, 1970.   |
|             | C8        | Aneja and Davies, "The synthesis of a spin-labelled glycero-phospholipid," <i>Chem. Phys. Lipids</i> , 4:60-71, 1970.  |
|             | C9        | Bahr, Deppe, Karas, Hillenkamp, "Mass spectrometry of synthetic polymers by UV-matrix-assisted laser desorption/ionization," <i>Anal. Chem.</i> , 64:2866-2869, 1992.  |
|             | C10       | Balch, Morris, Brooks, Sleight, "The use of N-(7-nitrobenz-2-oxa-1,3-diazole-4-yl)-labeled lipids in determining transmembrane lipid distribution," <i>Chem. Phys. Lipids</i> , 70:205-212, 1994.  |
|             | C11       | Bangham and Horne, "Negative staining of phospholipids and their structural modification by surface-active agents as observed in the electron microscope," <i>J. Mol. Biol.</i> , 8:660-668, 1964.   |
|             | C12       | Bangham, Standish, Watkins, "Diffusion of univalent ions across the lamellae of swollen phospholipids," <i>J. Mol. Biol.</i> , 13:238-252, 1965.   |

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*[Signature]*

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|             | C13       | Bartlett, "Phosphorus assay in column chromatography," <i>J. Biol. Chem.</i> , 234(3):466-468, March 1959.   |
|             | C14       | Beauchamp, Gonias, Menapace, Pizzo, "A new procedure for the synthesis of polyethylene glycol-protein adducts; effects on function, receptor recognition, and clearance of superoxide dismutase, lactoferrin, and $\alpha_2$ -macroglobulin," <i>Anal. Biochem.</i> , 131:25-33, 1983. |
|             | C15       | Blume and Cevc, "Liposomes for the sustained drug release <i>in vivo</i> ," <i>Biochim. Biophys. Acta</i> , 1029:91-97, 1990.  |
|             | C16       | Caffrey, "Kinetics and mechanism of the lamellar gel/lamellar liquid-crystal and lamellar/inverted hexagonal phase transition in phosphatidylethanolamine: A real-time x-ray diffraction study using synchrotron radiation," <i>Biochemistry</i> , 24:4826-4844, 1985.                 |
|             | C17       | Caffrey and Bilderback, "Kinetics of the main phase transition of hydrated lecithin monitored by real-time x-ray diffraction," <i>Biophys.J.</i> , 45:627-631, March 1984.   |
|             | C18       | Chattopadhyay, "Chemistry and biology of <i>N</i> -(7-nitrobenz-2-oxa-1,3-diazol-4-yl)-labeled lipids: fluorescent probes of biological and model membranes," <i>Chem. Phys. Lipids</i> , 53:1-15, 1990.   |
|             | C19       | Dao, McIntyre, Sleight, "Large-scale preparation of asymmetrically labeled fluorescent lipid vesicles," <i>Anal. Biochem.</i> , 196:46-53, 1991.   |
|             | C20       | de Gennes, "Conformations of polymers attached to an interface," <i>Macromolecules</i> , 13:1069-1075, 1980.   |
|             | C21       | Fattal, Nir, Parente, Szoka Jr., "Pore-Forming Peptides Induce Rapid Phospholipid flip-flop in membranes," <i>Biochemistry</i> , 33:6721-6731, 1994.   |

Examiner:

Kashu

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| INFORMATION DISCLOSURE STATEMENT<br><br>(Use several sheets if necessary) |  | Rajendra Aneja                         |                          |
|   |  | Filing Date:<br>August 13, 1997        | Group:<br>1502           |
| U.S. Patent Documents<br>See Page 1                                       |  | Foreign Patent Documents<br>See Page 1 | Other Art<br>See Page 1  |

**Other Art (Including Author, Title, Date Pertinent Pages, Etc.)**

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|             | C22       | Gombotz and Pettit, "Biodegradable polymers for protein and peptide drug delivery," <i>Bioconjugate Chem.</i> , 6:332-351, 1995.   |
|             | C23       | Gregoriadis, "Fate of injected liposomes: observations on entrapped solute retention, vesicle clearance and tissue distribution <i>in vivo</i> ," In: <i>Liposomes as Drug Carriers</i> , Wiley, New York, pp. 3-18, 1988.                                 |
|             | C24       | Griffin, "Calculation of "HLB" values of nonionic surfactants," <i>J. Soc. Cosmetic Chemists</i> , 1:311-326, 1949, as cited in <i>Biological Abstracts</i> , 27:1955, column 9941.  |
|             | C25       | Griffin, "Calculation of "HLB" values of nonionic surfactants," <i>Am. Perfumer Essential Oil Rev.</i> , 65(5):26-29, 1955, as cited in <i>Biological Abstracts</i> , 27:1955, column 9941.  |
|             | C26       | Herbette, Marquardt, Scarpa, Blasie, "A direct analysis of lamellar x-ray diffraction from hydrated oriented multilayers of fully functional sarcoplasmic reticulum," <i>Biophys. J.</i> , 20:245-272, 1977.   |
|             | C27       | Hope, Bally, Webb, Cullis, "Production of large unilamellar vesicles by a rapid extrusion procedure. Characterization of size distribution, trapped volume and ability to maintain a membrane potential," <i>Biochim. Biophys. Acta</i> , 812:55-65, 1985. |
|             | C28       | Hristova and Needham, "Physical properties of polymer-grafted bilayers," In: <i>Stealth® Liposomes</i> , Lasic and Martin eds., CRC Press, Boca Raton, FL, Ch. 5, pp. 35-49, 1995.   |
|             | C29       | Kenworthy, Hristova, Needham, McIntosh, "Range and magnitude of the steric pressure between bilayers containing phospholipids with covalently attached poly(ethylene glycol)," <i>Biophys. J.</i> , 68:1921-1936, May 1995.                                |

Examiner: *Kirk* Date Considered: *6/4/07*

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|             | C30       | Kenworthy, Simon, McIntosh, "Structure and phase behavior of lipid suspensions containing phospholipids with covalently attached poly(ethylene glycol)," <i>Biophys. J.</i> , 68:1903-1920, 1995.  |
|             | C31       | Kenworthy, Simon, McIntosh, "Effects of lipids with covalently attached polyethylene glycol on distearoylphosphatidylcholine bilayer structure," <i>Biophysical Journal, 38th Annual Meeting of the Biophysical Society</i> , New Orleans, Louisiana, USA, March 6-10, 1994.                 |
|             | C32       | Klibanov, Maruyama, Beckerleg, Torchilin, Huang, "Activity of amphipathic poly(ethylene glycol) 5000 to prolong the circulation time of liposomes depends on the liposome size and is unfavorable for immunoliposome binding to target," <i>Biochim. Biophys. Acta</i> , 1062:142-148, 1991. |
|             | C33       | Klibanov, Maruyama, Torchilin, Huang, "Amphipathic polyethyleneglycols effectively prolong the circulation time of liposomes," <i>FEBS Lett.</i> , 268(1):235-237, 1990.   |
|             | C34       | Kuhl, Leckband, Lasic, Israelachvili, "Modulation of interaction forces between bilayers exposing short-chained ethylene oxide headgroups," <i>Biophys. J.</i> , 66:1479-1488, 1994.   |
|             | C35       | Lasic, "Sterically stabilized vesicles," <i>Angew. Chem. Int. Ed. Engl.</i> , 33:1685-1698, 1994.  |
|             | C36       | Lasic and Barenholz, eds., "F. Liposomes in drug delivery," In: <i>Handbook of Nonmedical Applications of Liposomes, From Gene Delivery and Diagnostics to Ecology</i> , CRC Press, Boca Raton, FL., Vol. IV, pp. 308-309, 1996.   |
|             | C37       | Lasic, Martin, Gabizon, Huang, Papahadjopoulos, "Sterically stabilized liposomes *: a hypothesis on the molecular origin of the extended circulation times," <i>Biochim. Biophys. Acta</i> , 1070:187-192, 1991.   |

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| Examiner: | Kush | Date Considered: | 6/4/07 |
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|             | C39       | Lefkowitz, Stadel, Caron, "Adenylate cyclase-coupled beta-adrenergic receptors. Structure and mechanisms of activation and desensitization," <i>Ann. Rev. Biochem.</i> , 52:159-186, 1983.   |
|             | C40       | Lesieur, Grabielle-Madelmont, Paternostre, Ollivon, "Study of size distribution and stability of liposomes by high performance gel exclusion chromatography," <i>Chem. Phys. Lipids</i> , 64:57-82, 1993.  |
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|             | C44       | Mayer, Hope, Cullis, "Vesicles of variable sizes produced by a rapid extrusion procedure," <i>Biochim. Biophys. Acta</i> , 858:161-168, 1986.  |
|             | C45       | McIntosh, Magid, Simon, "Steric repulsion between phosphatidylcholine bilayers," <i>Biochem.</i> , 26:7325-7332, 1987.   |
|             | C46       | Mori, Klibanov, Torchilin, Huang, "Influence of the steric barrier activity of amphipathic poly(ethyleneglycol) and ganglioside GM <sub>1</sub> on the circulation time of liposomes and on the target binding of immunoliposomes <i>in vivo</i> ," <i>FEBS Lett.</i> , 284(2):263-266, June 1991. |

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|             | C48       | Needham, McIntosh, Lasic, "Repulsive interactions and mechanical stability of polymer-grafted lipid membranes," <i>Biochim. Biophys. Acta</i> , 1108:40-48, 1992.  |
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|             | C51       | Nolan, Magargee, Posner, Hammerstedt, "Flow cytometric analysis of transmembrane phospholipid movement in bull sperm," <i>Biochemistry</i> , 34:3907-3915, 1995.   |
|             | C52       | Parr, Ansell, Choi, Cullis, "Factors influencing the retention and chemical stability of poly(ethylene glycol)-lipid conjugates incorporated into large unilamellar vesicles," <i>Biochim. Biophys. Acta</i> , 1195:21-30, 1994. |
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|             | C55       | Small, "Polar lipids," In: <i>Handbook of Lipid Research, The Physical Chemistry of Lipids, From Alkanes to Phospholipids</i> , Plenum Press, New York, Ch. 4, p. 93, 1986a.   |
|             | C56       | Small, "Phospholipids," In: <i>Handbook of Lipid Research, The Physical Chemistry of Lipids, From Alkanes to Phospholipids</i> , Plenum Press, New York, Ch. 12, pp. 475-522, 1986b.   |

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|             | C58       | Szoka Jr. and Papahadjopoulos, "Procedure for preparation of liposomes with large internal aqueous space and high capture by reverse-phase evaporation," <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 75(9):4194-4198, September 1978.  |
|             | C59       | Winterhalter and Lasic, "Liposome stability and formation: Experimental parameters and theories on the size distribution," <i>Chem. Physics Lipids</i> , 64:35-43, 1993.  |
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|             | C61       | Woodle and Lasic, "Sterically stabilized liposomes," <i>Biochim. Biophys. Acta</i> , 1113:171-199, 1992.  |
|             | C62       | Woodle, Engbers, Zalipsky, "New amphipatic polymer-lipid conjugates forming long-circulating reticuloendothelial system-evading liposomes," <i>Bioconjugate Chem.</i> , 5(6):493-496, 1994.   |
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|             | C64       | Worthington, "The interpretation of low-angle x-ray data from planar and concentric multilayered structures. The use of one-dimensional electron density strip models," <i>Biophys. J.</i> , 9:222-234, 1969.   |
|             | C65       | Yatvin, Tegmo-Larsson, Dennis, "Temperature- and pH-sensitive liposomes for drug targeting," <i>Methods in Enzymology</i> , 149:77-87, 1987.  |
|             | C66       | Zalipsky, "Functionalized poly(ethylene glycol) for preparation of biologically relevant conjugates," <i>Bioconjugate Chem.</i> , 6:150-165, 1995.  |

**Examiner:**

Kirke

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